

REMARKS

Claims 1-2, 4-9, 11-23, 25-26, and 28-30, as amended, as well as new claims 31-35, are pending in this application for the Examiner's review and consideration. Claim 1 was amended to correct language to which Examiner objected and to recite manganese ascorbate as the manganese component (*See, e.g.*, Specification, page 16, lines 7-8). Claims 4-6 were amended to depend from claim 1, rather than canceled claim 3. Claim 4 was amended to clarify "mono- or poly- hydroxy acid" by removing "or tannic acid." Claim 11 was amended to correct grammatical errors arising from changes to the manganese component of independent claim 1. Claims 25 and 27 were amended to depend from claims 1 and 16, respectively, rather than canceled claim 24. Claim 28 was amended to recite copper sebacate as the copper component (*See, e.g.*, Specification, page 16, line 15). Claim 29 was amended to recite a selenium-amino acid complex as the selenium component (*See, e.g.*, Specification, page 16, lines 29-30). Claims 25-26 were amended to correct their dependency from cancelled claim 24 to pending claim 1. New claim 31 recites a cream, lotion, or ointment form of the dermatological agent of claim 1. This claim was listed in Appendix B of the December 9, 2002 Amendment in response to the Final Office Action, but was not mentioned in any other portion of that Amendment. Applicant therefore offers this claim as a new claim herein, to rectify the situation. Support for this new claim can be found, *e.g.*, at page 26 of the instant specification. New claim 32 contains the subject matter of pending claim 27, except with dependency on claim 30. New claim 33 recites an orally-administered dermatological composition containing components similar to those recited in claims 1 and 28-30 before they were amended herein (*See also, e.g.*, previously pending claim 22). New claims 34-35 recite topically-administered compositions similar to those recited in method claims of a related, co-pending matter, *i.e.*, U.S. Application No. 09/501,218. Support for these new claims can be found in the instant specification, *e.g.*, at pages 11-15 and 19-20. As no new matter has been added, Applicant respectfully requests that these amendments be entered at this time and submits that all claims are in condition for allowance.

THE PENDING REJECTION UNDER 35 U.S.C. § 103(a)

On pages 5-7 of the Final Office Action, claims 1, 2, 4-9, 11-23, and 25-30 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,891,440 to Lansky ("Lansky"), in view of U.S. Patent No. 5,985,300 to Crotty *et al.* ("Crotty") and U.S. Patent No. 6,071,543 to Thornfeldt *et al.* ("Thornfeldt"). Applicant respectfully traverses the rejection.

Lansky discloses an oral or topical phytoestrogen supplement prepared from pomegranate material, *e.g.*, pomegranate seeds, and schizandra berries and Chinese asparagus root. *See e.g.*, Lansky, col. 2, lines 49-56, and col. 3, lines 50-57. Lansky discloses an ointment prepared by pressing pomegranate seed to obtain oil and mixing the oil with

coconut milk to form a mixture. *See e.g.*, Lansky, col. 3, lines 7-11. Lansky also discloses that the oral supplement or ointment may be administered to relieve various symptoms in menopausal women or postmenopausal women. *See e.g.*, Lansky, col. 3, lines 50-56.

Crotty discloses a cosmetic product that is an adhesive strip to remove keratotic plugs and to deliver active ingredients to the skin. *See, e.g.*, Crotty, col. 2, lines 40-42. Crotty also teaches that a wetting agent, preferably water, is needed for the delivery of active ingredients to the skin. *See, e.g.*, Crotty, col. 5, lines 65 to col. 6, line 11.

Thornfeldt teaches compositions containing either pyridine thiols, metal sulfides, or metal oxides and methods for preventing signs and symptoms of aging using the disclosed compositions. *See, e.g.*, Thornfeldt, col. 3, lines 42-47. These compositions are applied to the skin or mucous membranes. *See, e.g.*, Thornfeldt, col. 3, lines 47-50.

In the Final Office Action, it is alleged that the present invention is obvious over Lansky, in view of Crotty and Thornfeldt. Applicant respectfully submits that combination of Lansky with Crotty and Thornfeldt does not teach all of the elements of the claimed invention. For example, Lansky does not disclose or suggest the presence of manganese ascorbate, copper sebacate, or selenium complexed with an amino acid. Thus, Lansky does not disclose all of the elements of the claimed invention.

Crotty does not remedy the shortcomings of Lansky. Crotty discloses adhesive strips that are applied to the skin. *See, e.g.*, Crotty, col. 2, lines 40-42. Crotty, similar to Lansky, does not disclose or suggest a composition containing a manganese, copper, or selenium component. Indeed, as acknowledged by the Examiner on pages 4-5 of the Final Office Action, the combination of Lansky and Crotty does not disclose all of the elements of the claimed invention.

Applicant respectfully submits that Thornfeldt does not remedy the shortcomings of the combination of Lansky and Crotty. Thornfeldt discloses compositions containing metal ions complexed with pyridine-thiols or are metal sulfides or metal oxides that allegedly reverse the visible signs of aging. At best, the compositions of Thornfeldt *may* disclose a manganese, copper, or selenium component that is complexed with pyridine-thiols, or that is reacted to form a sulfide or oxide. In contrast, the present claims recite manganese ascorbate as the manganese component; copper sebacate as the copper component; and/or selenium complexed with an amino acid as the selenium component. *See, e.g.*, Specification, page 16, lines 5-11; 12-19; and 27-31. Thus, the combination of Lansky with Crotty and Thornfeldt does not disclose all of the elements of the claimed invention.

Applicant respectfully notes that the Advisory Action recognized the difference between manganese ascorbate and the manganese compounds disclosed in Thornfeldt. *See* Advisory Action at page 2, lines 8-9. The Advisory Action, however, wrongly stated that “instant claims only recite manganese component and not manganese ascorbate.” *See* Advisory Action at page 2, lines 9-10. Applicant acknowledges that *independent claim 1, as previously pending*, did not recite manganese ascorbate, but, previously pending (and currently pending) claim 11 did (and still does) expressly recite manganese ascorbate, as does independent claim 1, as amended.

Furthermore, Applicant respectfully submits that one of ordinary skill in the art would not have been motivated to combine Crotty and Thornfeldt with Lansky to render obvious *oral* compositions, such as recited in claim 22 and new claim 33. Indeed, Crotty is directed to an adhesive strip and, accordingly, one of ordinary skill in the art would not have been motivated to combine it with the *oral formulation* of Lansky to disclose or suggest the *oral compositions* of claim 22 and new claim 33. *See, e.g., Crotty, col. 2, lines 40-42.* Clearly, an adhesive strip as disclosed in Crotty would not be combined with an *oral formulation* as disclosed in Lansky. Further, Thornfeldt only discloses applications to the skin or mucous membranes and, accordingly, cannot be combined with Lansky to disclose or suggest the *oral compositions* of claim 22 and new claim 33, *even without specific enumeration of the manganese, copper, and/or selenium component recited therein* (new claim 33). *See, e.g., Thornfeldt, col. 3, lines 47-50.* Accordingly, claims 22 and 33 directed to oral compositions are not rendered obvious by the cited references.

With regard to new claims 34-35, Applicant respectfully submits that they are also allowable. These claims recite compositions similar to those used in the methods claimed in related, co-pending application, U.S. Application No. 09/501,218 (“the ‘218 application”). New claims 34-35 recite a dermatological composition that comprises a hydrophobic moisturizer, a hydrophilic moisturizer, and a mono- or poly- hydroxy acid, in combination with a pomegranate extract (new claim 34) or a fruit extract and a transition metal (claim 35).

Applicant notes that, in the ‘218 application, claims directed to methods of treating dermatological conditions using the compositions recited in new claims 34-35 were acknowledged to be allowable over the combination of Crotty and Lansky in an interview with the Examiner. Similarly, the compositions recited in these claims should also be allowed.

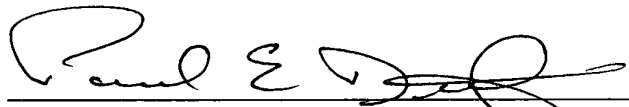
Indeed, all claims are believed to be in condition for allowance. Should the Examiner disagree, Applicant respectfully invites the Examiner to contact the undersigned

attorneys for Applicant to arrange for an interview in an effort to expedite the prosecution of this matter.

A fee of \$ 171. (small entity) is believed to be due for the addition of five (5) additional total claims and three (3) additional independent claims added herein over those claims for which payment has previously been remitted. Should any other fees be required, however, please charge the required fees to Pennie & Edmonds LLP Deposit Account No. 16-1150.

Respectfully submitted,

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Enclosures

APPENDIX A

MARKED UP VERSIONS OF THE AMENDED CLAIMS

Application No.: 09/501,217; Filed: February 10, 2000

1. (Four Times Amended) A dermatological agent for managing a dermatological condition in a patient comprising:
 - at least one fruit extract from pomegranate in an amount sufficient to neutralize free radicals;
 - a hydrophobic moisturizing agent in an amount sufficient to facilitate hydration of the patient's skin;
 - a hydrophilic moisturizing agent in an amount sufficient to facilitate hydration of the patient's skin;
 - a mono- or poly-hydroxy acid or tannic acid moisturizing agent in an amount sufficient to exfoliate at least a portion of the patient's skin;
 - [a manganese component] manganese ascorbate; and
 - a pharmaceutically acceptable carrier.
4. (Once Amended) The dermatological agent of claim [3] 1, wherein the mono- or poly- hydroxy acid is selected from the group consisting of glycolic acid, lactic acid, citric acid, [tannic acid,] salicylic acid, and mixtures thereof.
5. (Twice Amended) The dermatological agent of claim [3] 1, wherein the hydrophobic agent is selected from the group consisting of ceramide, borage oil, tocopherol linoleate, dimethicone, glycerine, and mixtures thereof.
6. (Once Amended) The dermatological agent of claim [3] 1, wherein the hydrophilic agent is selected from the group consisting of hyaluronic acid, sodium peroxylinecarbolic acid, wheat protein, hair keratin amino acids, and mixtures thereof.
11. (Twice Amended) The dermatological agent of claim 1, wherein the [manganese component is] manganese ascorbate [and] is present in an amount from about 0.5 to 10 weight percent, and wherein manganese is present in an amount from about 5 to 20 weight percent of the ascorbate complex.
25. (Once Amended) The dermatological agent of claim [24] 1, wherein the at least one fruit extract is selected from the group consisting of apricots, apples, pears, peaches, pineapples, papayas, pomegranates, cherries, kiwis, tangerines, grapes, oranges, and mixtures thereof.

27. (Once Amended) The dermatological agent of claim [24] 16, wherein the transition metal component comprises zinc.

28. (Once Amended) A dermatological composition for managing a dermatological condition in a patient comprising:

at least one fruit extract from pomegranate in an amount sufficient to neutralize free radicals;

a hydrophobic moisturizing agent in an amount sufficient to facilitate hydration of the patient's skin;

a hydrophilic moisturizing agent in an amount sufficient to facilitate hydration of the patient's skin;

a mono- or poly-hydroxy acid or tannic acid moisturizing agent in an amount sufficient to exfoliate at least a portion of the patient's skin;

[a copper component] copper sebacate; and

a pharmaceutically acceptable carrier.

29. (Once Amended) A dermatological composition for managing a dermatological condition in a patient comprising:

at least one fruit extract from pomegranate in an amount sufficient to neutralize free radicals;

a hydrophobic moisturizing agent in an amount sufficient to facilitate hydration of the patient's skin;

a hydrophilic moisturizing agent in an amount sufficient to facilitate hydration of the patient's skin;

a mono- or poly-hydroxy acid or tannic acid moisturizing agent in an amount sufficient to exfoliate at least a portion of the patient's skin;

[a selenium component] selenium complexed with an amino acid; and

a pharmaceutically acceptable carrier.